PTO-1390 (Rev. 12-2004) Approved for use through 03/31/2007. OMB 0651-0021

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#### ATTORNEY'S DOCKET NUMBER TRANSMITTAL LETTER TO THE UNITED STATES 029869.00002-US01 DESIGNATED/ELECTED OFFICE (DO/EO/US) U.S. APPOCATION NO. (If known, see 37 CFR 1.5) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED PCT/US2003/021700 9 July 2003 9 July 2002 TITLE OF INVENTION NOVEL COMPOUNDS, PHARMACEUTICAL COMPOSITIONS CONTAINING SAME, AND METHODS OF USE FOR SAME APPLICANT(S) FOR DO/EO/US Francis P. Kuhajda; Susan M. Medghalchi; Jill M. McFadden; and Jagan Thupari Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 2. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must 3. include items (5), (6), (9) and (21) indicated below. 4. The US has been elected (Article 31). 5. A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) is attached hereto (required only if not communicated by the International Bureau). b. has been communicated by the International Bureau. C. Х is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)). a. is attached hereto. b. has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)) are attached hereto (required only if not communicated by the International Bureau). b. have been communicated by the International Bureau. C. have not been made; however, the time limit for making such amendments has NOT expired. d have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)). 9 An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). An English language translation of the annexes to the International Preliminary Examination Report under PCT 10 Article 36 (35 U.S.C. 371 (c)(5)). Items 11 to 20 below concern document(s) or information included: 11. An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12 An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. A preliminary amendment. 14. An Application Data Sheet under 37 CFR 1.76. Х 15. A substitute specification. 16. A power of attorney and/or change of address letter. 17. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. A second copy of the published International Application under 35 U.S.C. 154(d)(4). 18. 19. A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). Other items or information: Copy of the International Search Report 20.

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|   | Approved for use through 05/3 1/2007. ONB 065 1-002                              |
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| U.S. APPLICATION  | 0/52  | 0°5°n  | 5                  | INTERNATIONAL APPLICATION NO. PCT/US2003/021700 |                |              | ATTOF          | ATTORNEY'S DOCKET NUMBER<br>029869.00002-US01 |          |  |
|---|---|--|--------------------|---|----------------|--------------|----------------|---|----------|--|
| 21. The following fees are submitted:   |   |  |                    |   |                |              |                |   |          |  |
| x a) Basic national fee\$300.00   |   |  |                    |   |                | 00.00        | \$             | 300.00  |          |  |
| b) Examination fee\$200.00  |   |  | \$                 | 200.00  |                |              |                |   |          |  |
| x c) Searc  | x c) Search fee\$500.00   |  |                    |   | \$             | 500.00       |                |   |          |  |
| TOTAL OF ABOVE CALCULATIONS = \$1000.00   |   |  |                    |   |                | \$           | 1,000.00       |   |          |  |
| Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. |   |  |                    |   |                |              |                |   |          |  |
| Total Sheets  | Extra sheets  | Extra sheets Number of each additional 50 or fraction thereof (round up to a whole number RATE |                    |   |                |              |                |   |          |  |
| 76 - 100 =  | /50   | =  |                    |   |                | x \$250.00   |                |   |          |  |
| Surcharge of \$ from the earliest   | 130.00 for furnish claimed priority d   | ning the oat<br>ate (37 CFF  | h or de<br>R 1.492 | eclaration later tha<br>(e)).                   | ın 30 mont     | hs           | \$             | 130.00  |          |  |
| CLAIMS  | ·   | R FILED  | NU                 | MBER EXTRA                                      | R              | ATE          |                |   |          |  |
| Total claim   |   | 6 - 20 =   | <u> </u>           | 26  | x              | 50.00        | \$             | 1,300.00                                      |          |  |
| Independent cla   |   | 7 - 3 =  | <u> </u>           | 4   | х              | 200.00       | \$             | 800.00  | <u> </u> |  |
| MULTIPLE DEF  | PENDENT CLAIN   | i(s) (if appli   |                    | TAL OF ABOVE                                    | CALCIU         | ATIONS -     | \$             |   | 0.000.00 |  |
| X Applicant   | claims small ent  | ity status.  |                    | CFR 1.27. The f                                 |                |              | \$             |   | 3,230.00 |  |
| are reduc   | ed by 1/2.  |  |                    | <del></del>                                     |                |              | <u> </u>       | \$ 1,615.00                                   |          |  |
| SUBTOTAL =  Processing fee of \$130.00 for furnishing the English translation later than 30 months  |   |  |                    |   | \$             |              | 1,615.00       |   |          |  |
| -   | t claimed priority of   | •  | -                  |   | 311 00 1110110 | +            | \$             |   |          |  |
| TOTAL NATIONAL FEE =  |   |  |                    |   | \$ 1,615.00    |              |                |   |          |  |
|   | Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property |  |                    |   |                |              |                |   |          |  |
| TOTAL FEES ENCLOSED =   |   |  |                    | \$  |                | 1,615.00     |                |   |          |  |
|   |   |  |                    |   |                |              | Amou<br>refund | int to be<br>ded:                             | \$       |  |
|   |   |  |                    |   |                |              | Amou<br>charg  | int to be<br>ed:                              | \$       |  |
| a. X A check in the amount of \$ 1,615.00 to cover the above fees is enclosed.  |   |  |                    |   |                |              |                |   |          |  |
|   | se charge my De<br>ver the above fe   | •  |                    | ppy of this sheet is                            |                | n the amount | of \$ _        |   |          |  |
| c. x The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any   |   |  |                    |   |                |              |                |   |          |  |
| overpayment to Deposit Account No. 50-0740 . A duplicate copy of this sheet is enclosed.  d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card  |   |  |                    |   |                |              |                |   |          |  |
| information should not be included on this form. Provide credit card information and authorization on PTO-2038.   |   |  |                    |   |                |              |                |   |          |  |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the International Application to pending status.                                   |   |  |                    |   |                |              |                |   |          |  |
| SEND ALL CORRESPONDENCE TO:   |   |  |                    |   |                |              |                |   |          |  |
| SIGNATURE:  N. Whitney Wilson   |   |  |                    |   |                |              |                |   |          |  |
|   |   |  |                    |   | NAME           | <b>.</b>     |                |   |          |  |
| CUSTOMER  | NUMBER: 26  | 353  |                    |   | יייים איייים   | CTDATION     |                | 8,661   |          |  |
| REGISTRATION NUMBER   |   |  |                    |   |                |              |                |   |          |  |
|   |   |  |                    |   |                |              |                |   |          |  |

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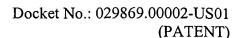
PTO-1390 (Rev. 12-2004)

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| U.S. APPLICATION  | 07520   | 50               | INTERNATIONAL A                     | APPLICATION N<br>JS2003/02 |                        | ATTORNEY'S DOCKET NUMBER<br>029869.00002-US01  |          |  |
|---|---|------------------|-------------------------------------|----------------------------|------------------------|--|----------|--|
| 21. The following fees are submitted:   |   |                  |                                     |                            |                        |  |          |  |
| x a) Basic  | national fee  | 00.00            | \$ 300.00                           | )                          |                        |  |          |  |
| x b) Examination fee\$200.00  |   |                  |                                     |                            | \$ 200.00              |  |          |  |
| x c) Search fee\$500.00   |   |                  |                                     |                            |                        | \$ 500.00  |          |  |
| 1   | OTAL OF ABOVE   | CALCUL           | ATIONS =                            | \$10                       | 00.00                  | \$ 1,000.00  |          |  |
| Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. |   |                  |                                     |                            |                        |  |          |  |
| Total Sheets  | Extra sheets  | Number<br>thereo |                                     |                            |                        |  |          |  |
| 76 - 100 =  | /50 =   |                  |                                     |                            | × \$250.00             |  |          |  |
|   | 30.00 for furnishing claimed priority date  |                  | or declaration later the .492 (e)). | nan 30 mont                | ths                    | \$ 130.00  | )        |  |
| CLAIMS  |   |                  | NUMBER EXTRA                        | R                          | ATE                    |  |          |  |
| Total claims  |   | 20 =             | 26                                  | X                          | 50.00                  | \$ 1,300.00  |          |  |
| Independent cla   | ENDENT CLAIM(s)   | -3 =             | 4                                   | +<br>+                     | 200.00                 | \$ 800.00<br>\$  | )        |  |
| MOETH LE DE   | ENDENT CERIMICS)  | (п арриса        | TOTAL OF ABOV                       |                            | ATIONS =               | S  | 3,230.00 |  |
| x Applicant are reduce  |   | status. Se       | e 37 CFR 1.27. The                  | fees indica                | ted above              | \$ 1,615.00  |          |  |
| u.o.rodao   | 00 Dy 72.   |                  |                                     | SUE                        | STOTAL =               | \$   | 1,615.00 |  |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).  |   |                  |                                     |                            |                        |  |          |  |
| TOTAL NATIONAL FEE =  |   |                  |                                     |                            | \$ 1,615.00            |  |          |  |
|   | Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property |                  |                                     |                            |                        |  |          |  |
|   |   |                  | TOTAL                               | FEES ENC                   | LOSED =                | \$   | 1,615.00 |  |
|   |   |                  |                                     |                            | Amount to be refunded: | \$   |          |  |
| ·   |   |                  |                                     |                            |                        | Amount to be charged:  | \$       |  |
| a. X A ch   | eck in the amount o   | f \$             | 1,615.00                            | to cover th                | ne above fees          | is enclosed.   |          |  |
| b. Plea   | se charge my Depo   | sit Accoun       | t No.                               | i                          | n the amount           | of \$  |          |  |
| to co   | ver the above fees.   | A duplica        | te copy of this sheet               | is enclosed                |                        |  |          |  |
| c. x The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0740 . A duplicate copy of this sheet is enclosed.  |   |                  |                                     |                            |                        |  |          |  |
| d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card Information should not be included on this form. Provide credit card information and authorization on PTO-2038.                      |   |                  |                                     |                            |                        |  |          |  |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the International Application to pending status.                                   |   |                  |                                     |                            |                        |  |          |  |
| SEND ALL CORRESPONDENCE TO:   |   |                  |                                     |                            |                        |  |          |  |
|   |   |                  |                                     | SIGN                       | ATURE:                 | N. Whitney Wilson  |          |  |
|   |   |                  |                                     | NAM                        |                        | The state of the s |          |  |
| CUSTOMER  | NUMBER: 2685  | 3                |                                     | 38,661 REGISTRATION NUMBER |                        |  |          |  |
|   |   |                  |                                     |                            |                        |  |          |  |



### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Francis P. Kuhajda et al.

Application No.: To be Assigned

(371 of Int'l. Appl. No. PCT/US2003/21700)

Group Art Unit: N/A

Filed: January 7, 2005

(Int'l Filing Date: July 9, 2003)

Examiner: Not Yet Assigned

For: NOVEL COMPOUNDS, PHARMACEUTICAL

COMPOSITIONS CONTAINING SAME, AND

METHODS OF USE FOR SAME

## TRANSMITTAL LETTER

#### **MS PCT**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Enclosed are the following items for filing in connection with the above-referenced Patent Application:

- 1. Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) Concerning a Submission under 35 U.S.C. 371 (in duplicate);
- 2. Application Data Sheet;
- 3. Copy of International Publication No. WO 2004/005277 A1 comprising: 66 pages of description; 11 pages of claims; and 12 sheets of drawings (Figs. 1-12);
- 4. Copy of the International Search Report;
- 5. Check No. 338996 for \$1,615.00 to cover:

DC: 1664686-1

10/520505 2112 Rec'd POT/PTO 0 7 JAN 2005

Application No.: To be Assigned (371 of Int'l. Appl. No. PCT/US2003/21700)

Docket No.: 029869.00002-US01

\$150.00 basic national stage fee;

\$250.00 search fee;

\$100.00 examination fee;

\$65.00 surcharge for late submission of the declaration;

2

\$1,050.00 additional claims fee; and

6. Two return receipt postcards.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-0740, under Docket No. 029869.00002-US01. A duplicate copy of this paper is enclosed.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 50-0740.

Dated: January 7, 2005

Respectfully submitted,

N. Whitney Wilson

Registration No.: 38,661

COVINGTON & BURLING

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Attorney for Applicant